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In the Supreme Court of the United States

OCTOBER TERM, 1962

No. 643

NATURE FOOD CENTRES, INC., HENRY F. ROSENBERGER, AND ANDREW G. ROSENBERGER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinions of the court of appeals (Pet. 19–24) and the district court (Pet. 17–18) are not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on November 13, 1962 (Pet. 25). The petition for a writ of certiorari was filed on December 7, 1962. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Section 352 of Title 21 provides that a drug is misbranded unless its labeling includes "adequate directions for use." The question presented is whether this provision is satisfied by "class notes" of a health food lecturer, when the notes did not even mention the drugs by name, but referred generally to the claimed usefulness of components of the drugs, when the lecturer went further than the notes in making oral claims for the drugs, and when the notes frequently did not accompany the drugs at the time they were sold.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*, provides in pertinent part:

Section 201 [21 U.S.C. 321]:

For the purposes of this Act—

* * * * *

(e) The term "person" includes individual, partnership, corporation, and association.

* * * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * * * *

Section 301 [21 U.S.C. 331]:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.

* * * * *

Section 303 [21 U.S.C. 333]:

(a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * *.

* * * * *

Section 502 [21 U.S.C. 352]:

A drug or device shall be deemed to be misbranded—

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *.

21 CFR 1.106(a) provides in pertinent part:

(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising * * *.

* * * * *

STATEMENT

An information filed in the District Court for the District of Massachusetts under Sections 301 and 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 and 333) alleged in thirteen counts that petitioners, Nature Food Centres, Inc., and two of its employees, had caused the illegal shipment in interstate commerce of drugs which were misbranded in violation of Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1)) (R. 8a–25a).[1] The information alleged that the misbranding consisted of the failure of the drugs to bear labeling providing adequate directions for use in that it did not state the diseases, purposes, and conditions for which the drugs were actually intended. The seven drugs involved were Colex (Counts 1 and 12) (R. 9a, 23a), C-Aminos (Counts 2 and 11) (R. 10a, 22a), Safflower Oil Capsules (Counts 3 and 13) (R. 11–12a, 24a), Hemo-Glo (Counts 4 and 9) (R. 13a, 19a), B-Amino-Complex (Count 5) (R. 14a), Super E Plus (Counts 6 and 8) (R. 15a, 18a), and GL–12 (Counts 7 and 10) (R. 17a, 21a).

The case was submitted to the trial court on stipulated facts and exhibits (R. 27a–46a). The drugs at issue were labeled as "dietary supplements" supplying various proportions of the vitamins, minerals, proteins, amino acids, and other substances needed for an adequate diet. As to some of the ingredients, such as isolencine, methionine, tryptophane, lecithin, and glutamic acid, the labeling stated "need in human

[1] "R." refers to the appendix to appellants' brief in the court of appeals. "R.A." refers to the appendix to appellee's brief in that court.

nutrition not established." The labels (Ex. 10a–16b) made no mention of any medical value for any of the products.[2]

Proof that the articles were intended for use as drugs was established by evidence of the claims made in oral lectures to promote their sale given by petitioner Andrew Rosenberger in principal cities where Nature Food had branch health food stores. The mode of operation (see R. 40a–42a) was to announce a free lecture and an offer of a free gift to anyone who attended (Ex. 6 and 7, R. 67a and 69a). Persons attending were invited to sign up for three more lectures, for which an admission fee was charged. So-called class notes (Ex. 1, 2, and 3a, R. 57a, 59a, 61a) were sold at these lectures, either as a part of the admission fee or for an extra fee (Stip. 47(B)(3)(c) and (d), R. 41a), but the notes were not made available in the stores where the products were regularly offered for sale (Ex. 20, pp. 59–60, R.A. 101a). The class notes consisted of lengthy discussions of parts of the body, various diseases, the importance of diet to health, the impossibility of obtaining from normal food the nutrients that are needed for good health, the part played by poor soil, fertilization, the use of sprays, and processing of food in reducing the nutritive value of ordinary foods, and the role of natural

[2] For example, the label for Safflower Oil, which is typical, stated (Ex. 12b):

Safflower Oil Capsules—

A pleasant source of unsaturated fatty acids as supplied by safflower oil and Vitamin B6, for use as a dietary supplement in deficiencies of essential fats.

vitamins, natural minerals, lipotropic agents, protein, barbados molasses, tortula yeast, millet, and other unique foods in preventing and treating diseases. The class notes did not refer specifically to any of the drugs involved in this case.

In the lectures themselves, the Nature Food products were identified by name for use in the treatment of various diseases and symptoms.[3] For example, Safflower Oil, which, on the label, was identified as a dietary supplement was, according to the information presented in the health lectures, for use in the prevention of coronary thrombosis, heart attacks, and arteriosclerosis (Ex. 17, p. 36, R.A. 76a; Ex. 18, p. 35, R.A. 79a; Ex. 19, p. 18, R.A. 83a; Ex. 21, pp. 20–21, R.A. 103a–104a; Ex. 23, p. 12, R.A. 109a). Other drugs were similarly labelled and similarly described in the lectures as intended for the treatment of serious diseases.

The trial judge found petitioners guilty, holding that the class notes constituted labeling, but that they did not comply with the statute's requirement of providing adequate directions for use (Pet. 17–18). The corporation was fined $10,000, and the individual petitioners were each fined $5,000 and sentenced to imprisonment for six months. The sentences were suspended in favor of probation for two years (R. 48a–51a).

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[3] Agents of the Food and Drug Administration attended the lectures and recorded the claims made for the product. Pertinent excerpts from the lectures were included in the government's appendix in the court below (R.A. 75a–116a). Copies of the lecture transcripts are filed with the court of appeals.

The court of appeals affirmed the conviction, holding that the references in the class notes did not satisfy the statutory command, both because they did not identify the drugs to which the claims were directed and because the directions for use in the notes fell far short of the oral claims made for the drugs in the lectures (Pet. 19–24). The opinion also stated, that, even if the directions for use in the notes had been adequate, they could not constitute labeling for the drugs sold in the Nature Food stores without accompanying notes.

ARGUMENT

Petitioners concede that the labelling on the drugs themselves did not constitute "adequate directions for use" as required by 21 U.S.C. 352. The only issue in this case, therefore, is whether the "class notes" which were available at lectures and intended to promote sale of the drugs constituted adequate labelling. We submit that these notes were not adequate for two separate reasons. First, the class notes, even if assumed to constitute labelling, were not adequate labelling both because they did not mention or identify the drugs and because they gave directions for use which fell short of the oral claims made to promote sales.[4] Second, the class notes could not constitute labelling as to the store sales where the notes did not accompany the drugs and were not associated with their sales. Both issues are essentially factual. We sub-

[4] Petitioners state (Pet. 4, note 1) that if the class notes constituted labelling, the government conceded in the district court that they could not be convicted on eight of the thirteen counts. No such concession, however, was made.

mit that the court of appeals properly held that petitioners' conviction was adequately supported by the evidence and that this determination does not call for further review.

1. The class notes made no mention at all of any of the drugs which Nature Foods sold. They did, however, describe the value and use of various substances which were included in the drugs. The inadequacy of this description in telling the purchaser of the use of the drugs themselves may be easily illustrated. C-Aminos, which is prepared from rose hips, was claimed by the lecturer to be effective in treating gouty arthritis (R.A. 75a, 102a). Petitioner argued in the trial court that the class notes provided adequate directions for this use in a full chapter of discussion on arthritis (Ex. 1, p. 27, R. 57a).[5] That chapter, however, states that arthritis is treated by drastic diet changes—by replacing meat and eggs with cottage cheese and related foods. There is no mention of C-Aminos (Ex. 1, p. 29). A reader trying to select a drug on the basis of the discussion would likely purchase B-Aminos or Hemo-Glo, which contain B-complex vitamins, not C-Aminos which contains Vitamin C and Amino-Acids.

Similarly, the lecturer claimed that B-Amino-Complex is to be used for a healthy skin. Petitioners rely (Pet. 12–13) for directions as to this use on a discussion of Vitamin B complex in the class notes, stating that niacin, which is listed under the ingredients of Vitamin B complex, is necessary for healthy

[5] Exhibit 1 was not even available for sale at the lectures (R. 42a; R.A. 78a–79a).

skin (Ex. 1, p. 9). However, here again, while the class notes discuss the B-group vitamins in relation to various conditions, they do not name specific products in relation to these conditions. Consequently, a consumer would be faced with a very real problem, if he should try to use the class notes as "directions for use." Both B-Amino Complex and Hemo-Glo contain the B-complex vitamins referred to in the class notes and the language in the class notes is as applicable to one as to the other. Such ambiguity is not the clear, understandable statement of intended uses required to comply with the statute's mandatory "adequate directions for use."

2. The regulations, 21 C.F.R. 1.106(a), *supra*, p. 3, provide that " 'adequate directions for use' means directions under which the layman can use a drug or device safely and for the purpose for which it is intended. Directions for use may be inadequate because * * * of omission * * * of (1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral * * * advertising * * *." This regulation, which spells out the natural meaning of the statute, has been upheld in several cases (see, *e.g.*, *United States* v. *Alberty Food Products*, 98 F. Supp. 23 (S.D. Cal.), affirmed, 194 F. 2d 463 (C.A. 9); *Colgrove* v. *United States*, 176 F. 2d 614 (C.A. 9), certiorari denied, 338 U.S. 911; *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C.A. 1), certiorari denied, 354 U.S. 923) and is not challenged here.

Petitioners' class notes clearly did not satisfy the statute as elaborated in the regulations. As the court of appeals held (Pet. 23), "the claims or purposes stated in the lectures and in the notes were substantially different." This determination is supported by the three examples which the court of appeals gave in its opinion (Pet. 23–24).

3. The court of appeals stated (Pet. 24) that "although by 'accompanying' documents a defendant may incur liability for false labeling even though they do not accompany all the products, this does not mean that independent documents can satisfy affirmative labeling obligations with respect to those products they do not accompany." Petitioners argue that this aspect of the decision gives the term "labeling" a dual meaning and thereby introduces unconstitutional uncertainty into the statute.

There has, however, been no holding giving the term "labeling" different meanings. Documents which accompany some articles may be false in their relationship to those articles even though they are obviously not false as to other articles which they do not accompany. On the other hand, documents may constitute adequate labeling as to articles which they accompany, but they obviously cannot be adequate as to articles which they do not accompany.

Petitioners rely on *Kordel* v. *United States*, 335 U.S. 345, *United States* v. *Urbuteit*, 335 U.S. 355, and *United States* v. *Urbuteit*, 336 U.S. 804. Those cases hold merely that documents may accompany an article even if they are not physically attached or are not in the same mail as long as they "were nonetheless

interdependent [or] parts of an integrated distribution program." 335 U.S. at 350. But independent documents far removed from the point of sale cannot satisfy the affirmative requirement that labeling for drugs bear adequate directions for use. A drug is misbranded for failure to bear adequate directions for use unless there is labeling material closely enough associated with the drug at the point of its sale to enable the prospective purchasers to learn "whether the drug is one which is prescribed, recommended, or suggested for their particular form of * * * ailment." This was the holding in *Alberty Food Products Co.* v. *United States,* 185 F. 2d 321, 325 (C.A. 9), which was followed by the court below. See also *Alberty Food Products* v. *United States,* 194 F. 2d 463 (C.A. 9). In this case, the class notes could not constitute adequate labeling since they were available only to those who bought them at the lectures and were never available in the retail stores where the products were merchandised (Ex. 20, pp. 59–60, R.A. 101a).

There is no unconstitutional uncertainty introduced into the statute by the holding that the class notes were not sufficient to provide adequate directions for use. Honest enterprise can readily meet the statutory requirements by including in the promotional material used at the point of sale the same claims that are used in advertising, written or oral, to promote the sale.[6]

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[6] For a good discussion of the purpose of 21 U.S.C. 352(f)(1) in promoting honest enterprise, see *United States* v. *Various Quantities of Articles of Drug*, 83 F. Supp. 882, 885 (D.C. D.C.).

CONCLUSION

For the foregoing reasons we respectfully submit that the petition for a writ of certiorari should be denied.

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